

REMARKS

Reconsideration of this application, as amended, is respectfully requested. As shown in the attached listing of the claims, claims 1-14 have been withdrawn, claims 27 and 28 have been cancelled, claims 15, 18, 22 and 23 have been amended, and new claims 29-34 have been added. The amended claims do not add any new matter and are supported by the application as originally filed. Applicants reserve the right to reincorporate any cancelled or otherwise presently unclaimed subject matter in this application as appropriate or to prosecute the same in subsequently filed applications. Consideration and entry of these amendments is respectfully requested.

Claim Objections

Claim 18 was objected to as being dependent upon itself; this claim has been amended and therefore the objection is moot.

Rejections under 35 USC 112, second paragraph

Claims 18 stands rejected under 35 U.S.C. 112, second paragraph as being indefinite. Claim 17 has been withdrawn. Claim 18 has been rewritten in independent form and refers to both ATCC and ALVAC(2). Withdrawal of this rejection is therefore respectfully requested.

Rejections under 35 USC 112, first paragraph

Claims 15, 18, 22, 23, 27 and 28 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection as indicated below.

Claims 27 and 28 have been cancelled; this rejection is therefore moot as to claims 27 and 28. As to the rejection of claims 15, 18, 22 and 23, the Examiner stated that a deposit of ALVAC and ALVAC(2) made under the Budapest Treaty would satisfy this rejection. The Examiner is correct that ALVAC has been deposited with the ATCC under the Budapest Treaty, the deposit having accession number VR-2547. As to ALVAC(2), evidence that a deposit has been made under the Budapest Treaty will be supplied to the Examiner before the date of issuance of any patent resulting from this

application, in accordance with 37 C.F.R. 1.809(b)(1). With this assurance, this rejection should be withdrawn in accordance with MPFP 2411.02.

Rejection under 35 U.S.C. 102(b)

A. The "Paoletti" reference

Claims 15, 18, 22, 23, 27 and 28 stand rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti (U.S. Pat. No. 5,833,975). Applicants respectfully traverse this rejection as discussed below.

Claims 27 and 28 have been cancelled with the amendment. The rejection as to these claims is therefore moot.

As to claims 15, 18, 22 and 23, the Examiner alleges that the claimed compositions are anticipated by Paoletti. It is also alleged that the recited methods do not lend patentability to the claimed composition unless the method results in a structurally and functionally different product than that disclosed by Paoletti. Applicants respectfully disagree. While ALVAC and ALVAC(2) have been previously produced using the method described by Paoletti, the use of avian embryonic stem cells yields ALVAC and ALVAC(2) compositions having more desirable profiles than previously described compositions. The methods of Paoletti rely on the use of chicken embryo fibroblasts to produce ALVAC (see Paoletti, col. 16, lines 28-37). Those of skill in the art have stated that the methods described in the instant claims provide a "safer . . . alternative to the use of . . . chicken primary embryonic fibroblasts for the production of a large amount of viral vectors and viruses for the manufacture of viral vaccines, such as poxviruses . . ." (www.vivalis.com; attached as **Appendix A**). Both of these art-recognized attributes are only relevant in that the instantly claimed ALVAC and ALVAC(2) products provide a significant structural and functional advantage over previously available products. Accordingly, Applicants respectfully maintain that the product is distinct from that of Paoletti and that these 35 U.S.C. 102(b) rejections are improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

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Aug. 04 2006 10:45AM . P9

B. The "Snow" reference

Claims 15, 22, 23, 27 and 28 stand rejected under 35 U.S.C. 102(b) as being anticipated by Snow (*Bay Area Reporter*, National Institutes of Health: ALVAC Prime and Boost, HIV Vaccine Handbook, Approaches, 1998, pp. 201-208). Applicants respectfully traverse this rejection as discussed below.

Claims 27 and 28 have been cancelled with the amendment. The rejection as to these claims is therefore moot.

As to claims 15, 22 and 23, Applicants respectfully traverse this rejection. As described above, the compositions have art-recognized structural and functional advantages over previously available compositions. Snow is completely silent as to the instantly claimed new compositions. As such, Applicants believe the instant rejections under 35 U.S.C. 102(b) are improper and request withdrawal of the same.

CONCLUSIONS

Applicants respectfully request consideration and entry of this reply. Applicants believe the claims are in condition for allowance and request that a Notice of Allowance be issued as soon as possible. The Examiner is encouraged to contact the Applicants' undersigned representative if it is believed doing so would expedite prosecution of this application.

Date: August 4, 2006

Respectfully submitted,



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Aug. 04 2006 10:45AM P10.

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APPENDIX A

Manufacturing

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opportunity

News

Contact

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Viral Vaccines

Production of pre-clinical and clinical lots of viral vectors and vaccines



Vivalis' offering includes:
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cell-based platform for pre-clinical
and cGMP clinical lots of viral vectors
and viruses. The Expi™ platform
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effective alternative to the use
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embryos to generate virus stocks for
the production of large amounts
of viral vectors and vaccines.
The manufacturer of viral vaccines
such as: Influenza Vaccine (IIV),
Zovirax® (Aciclovir) Vaginal
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Zoster Vaccine (Varicella),

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